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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,998	09/29/2005	Yasuhiko Tabata	3691-0119PUS1	8785
2292 7590 08/27/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER SAOUD, CHRISTINE J	
			ART UNIT 1647	PAPER NUMBER
			NOTIFICATION DATE 08/27/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

**Office Action Summary**

Application No.

10/528,998

Applicant(s)

TABATA ET AL.

Examiner

Christine J. Saoud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 1-2 and 3-4 in part is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 and 4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/24/05, 3/20/06.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Group III in the reply filed on 07 June 2007 is acknowledged. The traversal is on the ground(s) that the restriction between the inventions of Groups III and IV is a species restriction since both Groups include the same claims. This is not found persuasive because a protein and the gene encoding the protein are not considered species of one another. Rather, they are completely different compounds, having distinct structure and distinct function based on their structural features. Furthermore, art for the administration of a protein for the treatment of a condition would not anticipate claims to treatment by administration of a gene and vice versa. Therefore, there is a serious burden of search for the two distinct methods. Furthermore, just because multiple compounds could be included in a single claim does not make them "species" of the same invention. For example, a claim to "a chair, a computer, an alcohol, a nucleic acid molecule, a rat, and a plant" does not make these objects/compounds species of one another, but rather, the claim is an improper Markush claim because there is no common structure which provides for a common function.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-2 and claims 3-4, in part, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 07 June 2007.

### ***Claim Objections***

Claims 3 and 4 are objected to because of the following informalities: they include non-elected subject matter. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 3 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 00/13710 (Jennings et al.).

Jennings et al. teach a method of treating coronary artery disease by the administration of a hydrogel composition comprising a water-miscible anionic polymer comprising bFGF (see claims 33 and 34). The claims do not specifically recite that the

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polymer is gelatin, however, it seems that gelatin would be encompassed by the claims, and therefore, the claims are anticipated by Jennings et al.

Claims 3 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Pat. No. 6,732,738 (Komeda et al.).

Komeda et al. teach the treatment of patients with coronary artery disease by the administration of bFGF in a gelatin hydrogel (see column 1-2). Therefore, the claims are anticipated by the prior art of record.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/13710 (Jennings et al.) in view of Ikada et al. (U.S. Pat. No. 6,831,058).

The disclosure of Jennings et al. is as provided above. Jennings et al. does not specifically recite the hydrogel as being gelatin.

Ikada et al. teach hydrogels of gelatin containing bFGF. The bFGF hydrogel is useful for treating a number of conditions, including promotion of vascularization. Because Jennings et al. teach that bFGF containing hydrogels would be useful for the treatment of coronary artery disease, it would have been prima facie obvious to use hydrogels of gelatin containing bFGF, as taught by Ikada et al., in the method of Jennings et al. for the treatment of coronary artery disease because Ikada et al. teach that their hydrogels are useful for promotion of vascularization. One would be motivated to use the hydrogels of Ikada et al. because Ikada et al. teach the benefits of the gelatin-bFGF hydrogels. One would have a reasonable expectation of success in using the hydrogels of Ikada et al. in the method of Jennings et al. because the compositions appear to be very similar and have similar biological properties. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

### ***Conclusion***

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHRISTINE J. SAOUD  
PRIMARY EXAMINER

*Christine J. Saoud*